Patent
Attorney's Docket No.: 7009742001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Reexamination of	)	**APPEAL 2010-001150**
	)	
David FIKSTAD *et al.*	)	Group Art Unit: 1618
	)	
Application No.: 09/871,318	)	Examiner: Micah Paul Young
	)	
Filed: May 31, 2001	)	Confirmation No.: 1207
	)	
For: TRANSDERMAL DELIVERY OF LASOFOXIFENE	)	
	)	

REQUEST FOR REHEARING PURSUANT TO 37 C.F.R. § 41.52

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

Appellants hereby request rehearing pursuant to 37 C.F.R. § 41.52. This Request for Rehearing is being filed within two months of the Board's Decision on Appeal in Appeal No. 2010-001150 decided March 23, 2011.

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I. ARGUMENT

Pursuant to 37 C.F.R. § 41.52, Appellants hereby request reconsideration of the Board's Decision of March 23, 2011. The following points were misapprehended and/or overlooked in the Board's decision.

First, on page 6, line 9 through page 8, line 18, of the Board's Decision ("the Decision") the Board stated that:

> [w]e adhere to our previous conclusion that, in view of these disclosures, a person of ordinary skill in the art would have considered it obvious to administer Lasofoxifene using Ebert's transdermal drug delivery device, because Ebert discloses that its device is suitable for administering a variety of drugs and Ke expressly suggests transdermal delivery of a composition comprising Lasofoxifene.

The Board then analyzed the declaration submitted under 37 C.F.R. §1.132 by Dr. Andrew Coop, Ph.D[1] ("the Coop Declaration") in view of this previous decision. Such an analysis is contrary to the procedure set forth by the Court of Appeals for the Federal Circuit requiring that all evidence be considered anew.

Second, on page 5, lines 13-18, of the Decision, the Board stated that:

> "[a] presumption arises that both the claimed and unclaimed disclosures in a prior art patent are enabled." *Amgen, Inc. v. Hoechst Marion Rouseel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003). After a rejection is made based on the presumptively enabled disclosure of a prior art patent, the applicant "can then overcome that rejection by proving that the relevant disclosures of the prior art patent are not enabled." *Id.*

The Board's reliance on U.S. Patent No 5,662,925 (Ebert *et al.*) as providing a presumptively enabled disclosure does not take into account Dr. Coop's unrebutted testimony as to the unpredictability inherent in formulating transdermal drug delivery

[1] *See* Applicant's Appeal Brief at Exhibit A.

system. In view of Dr. Coop's unrebutted testimony, it would require undue experimentation on behalf of one of ordinary skill in the art to combine Ebert et al. with Cormier and Ke in order to practice the claims currently under appeal.[2]

A. Rebuttal Evidence to an Obviousness Assertion Must be Considered Anew

The instant application was the subject of Appeal No. 2008-3445 that was decided on August 28, 2008. In that decision, the Board affirmed the Examiner's rejections of claims 3-5, 17, 22-24 and 28-40 and reversed the rejection of claims 14, 18, 19 and 25-27, entering a new ground of rejection and reopening prosecution.

In response to the new ground of rejection, Appellants submitted the Coop Declaration as evidence that one of ordinary skill in the art would not find the claimed transdermal device and methods for delivering Lasofoxifene to be obvious in view of the combination of the Cormier, Ke, and Ebert et al. publications cited. Dr. Coop testified that the Examiner's assertions of obviousness were based on unwarranted assumptions. Dr. Coop also testified that one of ordinary skill in the art would conclude that the combination of Lasofoxifene in the claimed transdermal drug delivery device and the related methods of treatment would be unpredictable and non-obvious.

When an Applicant presents rebuttal evidence to a previously uncontradicted assertion of obviousness, that assertion is dissipated. *In re Piasecki*, 745 F.2d 1468, 1472; 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). As a result, "the Examiner must consider all of the evidence anew" because an earlier decision should not "be considered as set in concrete" with the rebuttal

[2] Because the Board raised the presumption of Ebert *et al.* having an enabled disclosure for the first time at the Oral Hearing on March 15, 2011 and in the Decision, arguments in this regard are proper in accordance with 37 C.F.R. § 41.52(a)(2) and/or (3).

evidence being "evaluated only on its knock-down ability." *Id.*

The basis for the Federal Circuit's holding lies in the fact that "[a]n analytical fixation on an earlier decision can tend to provide that [previous] decision with an undeservedly broadened umbrella effect." *Id.* quoting *In re Rhinehart*, 531 F.2d 1048, 1052; 189 U.S.P.Q. 143, 147 (CCPA 1976). Therefore, a proper analysis "will rest upon [an] evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached by an earlier board upon a different record." *Id.* at 1472-1473.

In the final Office Action that issued in this case on December 12, 2008, the Examiner relied on the Board's decision dated August 28, 2008 in rejecting the claims. He did not perform any analysis evaluating all the evidence anew. *See* final Office Action Dated December 12, 2008 at pages 4-6.

The same holds true for the Examiner's Answer in the instant appeal. There, the Examiner reiterated the asserted obviousness rejection and summarily stated that Dr. Coop's testimony was insufficient to overcome the obviousness rejection. *See* Examiner's Answer dated August 13, 2009 at pages 4-7. Nowhere did he perform a new analysis evaluating all of the evidence along with the Coop declaration.

Finally, in the Decision dated March 23, 2011, the Board adhered to its previous conclusion as set forth in the Decision dated August 28, 2008 where it was held that the claims were obvious in view of Ebert et al. and Ke. *See* Decision on Appeal dated March 23, 2011 at page 6. The Board never considered all of the evidence anew along with the testimony of Dr. Coop. Such an analysis is at odds with the procedure mandated by the Federal Circuit when an applicant presents rebuttal evidence as to the non-obviousness of pending claims. *In re Piasecki*, 745 F.2d at 1472.

In both the Examiner's rejections and the Appeal at hand, the Decision in the previous Appeal dated August 27, 2008 formed the basis for finding that the claims at issues were obvious with the Coop declaration being evaluated only on its ability to overturn that obviousness determination. Such an analysis is improper. *Id.* Instead, a proper analysis would consider all of the evidence of record including Dr. Coop's testimony concurrently in making a determination under 35 U.S.C. §103(a).

What's more, such an analysis would follow the procedure set forth in the MPEP at 2144.08 II.A.4.(d) requiring the Examiner to consider similarities in chemical structure when considering the non-obviousness of claims. While this analysis was also never conducted by the Examiner, it would have allowed each of the indicia of non-obviousness raised in Dr. Coop's testimony to be addressed.

Because the proper procedure that the Federal Circuit has set forth for analyzing rebuttal evidence to an assertion of obviousness was not adhered to either during prosecution or the appeal, Appellants respectfully request the Board to modify its decision to perform a proper analysis considering all of the evidence anew and to follow the procedures set forth in MPEP 2144.08 II.A.4.(d). Appellants submit that a proper analysis consistent with the Federal Circuit's guidelines that considers all of the evidence anew and in accordance with the MPEP will demonstrate that the claims at issue are non-obvious. Alternatively, Appellants respectfully request the Board to remand the currently pending claims to the Examiner to reopen prosecution and perform such an analysis.

B. In its Presumption that the Ebert Disclosure is Enabled, the Board Did Not Consider Whether or Not Undue Experimentation Would be Required From the Perspective of One of Ordinary Skill in the Art

In the Decision on Appeal, the Board stated that "a presumption arises that both the claimed and unclaimed disclosures in a prior art patent are enabled." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003). *See* Decision on Appeal at page 5. The Board then stated that:

> Ebert's Disclosure that numerous drugs can be delivered using its transdermal delivery device, and Ke's disclosure that Lasofoxifene can be administered using any conventional transdermal dosage form, are presumed to be enabled by the disclosures of Ebert and Ke. *Amgen*, 314 F.3d at 1355. The only evidence that Appellants have provided to rebut that presumption is the Coop Declaration, which does not provide an adequate factual basis on which to conclude that undue, rather than routine, experimentation would have been required to administer Lasofoxifene transdermally.
>
> *See* Decision on Appeal at page 8.

The presumption of enablement is rebuttable. The Federal Circuit has held that an Applicant can rebut the presumption of enablement by demonstrating that the relevant disclosures of a prior art patent are not enabled. *Amgen*, 314 F.3d at 1355. An enablement analysis requires "considering whether or not a prior art reference requires undue experimentation... from the perspective of a person of ordinary skill in the art." *Amgen Inc. v. Hoechst Marion Roussel*, 457 F.3d 1293, 1306-1307; 79 U.S.P.Q.2D 1705 (Fed. Cir. 2006).

In the present case, Appellants followed this procedure by submitting the Coop Declaration. The effect of Dr. Coop's testimony on the presumption of enablement, however, was not fully considered by the Board. Dr. Coop testified regarding the unpredictability in the art inherent in combining the different compounds disclosed in Ke and Cormier with the transdermal drug delivery system described in Ebert et al. For example, Dr. Coop testified as

follows:

- "In sum, each of these differences in chemical make up of these compounds introduces a layer of *unpredictability* to the use of these compounds, especially with regard to formulations. And this *unpredictability* would then transcend to the *unpredictability* of the kinetics by which a drug passes out of the matrix and into the patient receiving therapy." *See* Coop Declaration at paragraph 11.
- "In addition to the layers of *unpredictability* with regard to the chemical make-up of compounds, there is also *unpredictability* in the transdermal device in itself. For example, since each of the compounds listed in the Cormier, Ke and Ebert publication possess certain qualities with regard to solubility, pH etc., these would require modifications of the device that would require the differences in how each drug would interact with the other compounds or adjuvants in the formulation as well as the phase distribution in the matrix and the release form the matrix to be accounted for. As a result, the material make-up of the device would have to be varied to prevent degradation of the drug, increase stability of the drug, and provide bioavailability of the drug to the patient. All of which are *unpredictable* factors that may or may not lend a drug to being formulated for transdermal delivery." *See* Coop Declaration at paragraph 12.
- "In view of these *unpredictable* considerations in formulating a transdermal device for the delivery of lasofoxifene, I believe that one who is skilled in the field, would not recognize that the topical administration of an aqueous solution of lasofoxifene as described in Ke et al. would in any way *predictably* dictate that the same concept would translate to the transdermal delivery of lasofoxifene using

the device and methods as set forth in claims 14, 18, 19, and 25-27. In fact, I believe that the topical administration of an aqueous solution of any drug would not be suggestive of whether that drug could be incorporated into a transdermal delivery device because many *unpredictable* factors must be taken into account not only with the drug, but also with the device itself as discussed above." *See* Coop Declaration at paragraph 13.

- "Therefore, it is my opinion that one who is skilled in the field would not find the transdermal device and methods for delivering lasofoxifene as set forth in claims 14, 18, 19 and 25-27 to be obvious in view of the combination of the Cormier, Ke and Ebert publications. This is because several assumptions must be made based on the *unpredictable* components would lead one who is skilled in the field to conclude that the combination of lasofoxifene in a transdermal drug delivery device and related methods of treatment *would not be predictable* based on their established functions." *See* Coop Declaration at paragraph 14.

Dr. Coop's testimony regarding *unpredictability* is significant to an enablement analysis because the scope of the required enablement varies inversely with the degree of predictability involved. *See, e.g., Chiron Corp. v. Genentech*, 363 F.3d 1247, 1254; 70 U.S.P.Q.2d 1321, 1326 (Fed. Cir. 2004); *See also*, MPEP 2164.03. Dr. Coop's testimony evidences that the overly broad disclosure in Ebert et al. is not enabled because one of ordinary skill in the art would not expect to combine it with the teachings of Ke and Cormier without undue experimentation.

In fact, the Board's Decision on Appeal does not address any of Dr. Coop's testimony as to the unpredictability of formulating a transdermal drug delivery system in view of the Ebert et al., Ke and Cormier publications cited. Nor does the Board offer any evidence of its own to

rebut the testimony of Dr. Coop. As a result, Dr. Coop's testimony stands as uncontroverted evidence of the unpredictability of modifying the Ebert et al. disclosure in order to formulate a transdermal drug delivery system that could incorporate the drugs disclosed in either Cormier or Ke by one of ordinary skill in the art.

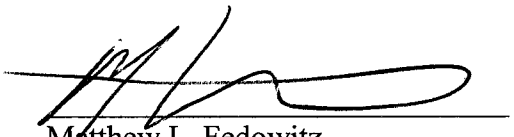
In light of this uncontroverted evidence, and of the fact that it was not fully considered by the Board, Appellants respectfully request the Board to modify its decision to take into account the uncontroverted evidence of undue experimentation. Alternatively, Appellants respectfully request the Board to remand the application to the Examiner reopening prosecution to so that the Examiner may address the uncontroverted evidence set forth in the Coop Declaration.

II. CONCLUSION

Because a proper analysis of the rejection under 35 U.S.C. § 103(a) was not conducted in light of the Coop Declaration and because the Coop Declaration is uncontroverted evidence that it would require undue experimentation to combine the publications cited, the Board's Decision should be modified.

The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 50-4047.

Respectfully submitted,
BINGHAM MCCUTCHEN, LLP

Date: May 20, 2011 By: 

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